UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR WARMING PRODUCTS LIABILITY LITIGATION This Document Relates To: All Actions	MDL No. 15-2666 (JNE/FLN) **PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION TO OVERRULE VITAHEAT MEDICAL LLC'S RELEVANCY OBJECTION TO SUBPOENA**

INTRODUCTION

Discovery continues to reveal alarming facts about the safety hazards of forced-air warming. [redacted][1] Until three months ago, however, Defendants had produced little to no evidence regarding VitaHEAT Medical, LLC ("VitaHEAT Medical"), the manufacturer of the so-called "UB3," a patient-warming device that uses "conductive heat [to] warm patients without circulating air."[2] Defendants had no relationship to VitaHEAT Medical at the beginning of this multidistrict litigation or during the initial phases of fact discovery.

[1] See, e.g., 3MBH00001336–37 [redacted], attached as Exhibit A.

[2] See VitaHEAT Medical Homepage (website no longer available), attached as Exhibit B.

But that changed on or around October 21, 2016, when 3M reached "an agreement with VitaHEAT Medical to be the exclusive United States distributor of the VitaHEAT UB3."[3]

Soon after learning that 3M had acquired distribution rights to an air-free warming device rather than a forced-air warming device, Plaintiffs served VitaHEAT Medical with a Rule 45 subpoena to produce documents regarding the design, clearance, and testing of the UB3, among other things. VitaHEAT Medical objected to these straightforward discovery requests under the guise that the UB3 has no relevance whatsoever to the claims or issues in this litigation. Plaintiffs now move the Court to overrule VitaHEAT Medical's relevancy objection and to compel VitaHEAT Medical to comply with reasonable requests.

BACKGROUND

[redacted][4]

[redacted][5]

[3] See VitaHEAT Medical Press Release (Oct. 21, 2016): http://vitaheatmedical.com/3m-agreement-with-vitaheat-medical-brings-mobile-patient-warming-to-industrys-largest-portfolio-of-normothermia-solutions/, attached as Exhibit C.

[4] See 3MBH00554405–06, attached as Exhibit D.

[5] Id.

[redacted][6] [redacted] [redacted] [redacted][7] They did so despite the great weight of evidence that forced-air warming was no better—and even worse—than air-free patient warming.[8] [redacted] [redacted][9] [redacted] [redacted] [redacted][10] [redacted]

[6] See 3MBH00021225–38 [redacted], attached as Exhibit E.

[7] [redacted] See, e.g., 3MBH00000325 [redacted], attached as Exhibit F.

[8] The work of Dr. Daniel Sessler—3M's long-standing consultant and Scientific Advisory Board member—is instructive in this regard. See Sessler, D., et al., Resistive-Heating and Forced-Air Warming Are Comparably Effective, Anesthesia & Analgesia, 2003;96:1683–1687, attached as Exhibit G; see also Sessler, D., et al., A Randomized Comparison of Intraoperative PerfecTemp and Forced-Air Warming During Open Abdominal Surgery, Anesthesia & Analgesia, 2011;113:1076–1081, attached as Exhibit H.

[9] See 3MBH01601967–78, attached as Exhibit I.

[10] See 3MBH01601971, attached as Exhibit I.

[redacted][11][redacted][12]

[redacted][13]

[redacted]

[redacted][14][redacted]

[redacted][15]

[redacted]

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[redacted][16][redacted]

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Based on independent testing, 3M even learned that the "there was no [statistically significant] difference between intra-operative and recovery room temperatures between

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[11] See id.

[12] See 3MBH01601973–74, attached as Exhibit I.

[13] See 3MBH01250816–24, attached as Exhibit J.

[14] See id.

[15] See 3MBH01250822, attached as Exhibit J.

[16] See 3MBH01250823, attached as Exhibit J.

[17] See 3MBH01250822, attached as Exhibit J.

patients" who were warmed by its very own Bair Hugger versus the UB3.[18] [redacted]

[redacted][19]

3M did just that on October 21, 2016. Contemporaneous press releases made clear that "3M ha[d] reached an agreement with VitaHEAT Medical to be the exclusive United States distributor of the VitaHEAT UB3 patient warming system."[20] The press releases further explained [redacted] that 3M had "evaluated a number of warming technologies," but the "design and safety features of the [UB3] really made it stand out compared to other conductive products currently on the market."[21]

Plaintiffs deposed key 3M employees in order to learn more about the UB3 and the distribution agreement. Yet Plaintiffs learned nothing more than what was otherwise apparent on the face of the press releases. [redacted]

[redacted][22] Michelle Hulse Stevens, the Chief Medical Officer of 3M's Infection Prevention Division, surprisingly knew even less about the agreement. [redacted]

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[18] See 3MBH01566286–97, attached as Exhibit K.

[19] See 3MBH0054405, attached as Exhibit D.

[20] See VitaHEAT Medical Press Release (Oct. 21, 2016): http://vitaheatmedical.com/3m-agreement-with-vitaheat-medical-brings-mobile-patient-warming-to-industrys-largest-portfolio-of-normothermia-solutions, attached as Exhibit C.

[21] Id.

[22] See Van Duren Dep., at 10:18-12:8, attached as Exhibit L.

[redacted][23] Accordingly, Plaintiffs subpoenaed VitaHEAT Medical on December 30, 2016.

The Rule 45 subpoena requested VitaHEAT Medical to produce: (1) all documents constituting or relating to the design history of the UB3; (2) all documents constituting or relating to testing of the UB3; (3) all documents constituting or relating to comparison testing conducted by VitaHEAT Medical of the UB3 to other warming devices, including the Hot Dog and the Bair Hugger; and (4) all documents relating to the agreement between VitaHEAT Medical and 3M under which 3M became the sole distributor of the UB3.[24]

Blackwell Burke P.A., on behalf of VitaHEAT Medical, objected to the subpoena on January 13, 2017.[25] VitaHEAT Medical listed boilerplate objections to the breadth, clarity, and proportionality of the requests, and it globally objected to the relevancy of Plaintiffs' requests in light of the claims and issues in this litigation.[26] Citing the Court's November 23, 2016 Order granting in part and denying in part Defendants' motion to compel discovery from Dr. Scott Augustine and his entities, VitaHEAT Medical asserted that "product design documents of a medical device not identified by any party, including

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[23] See Hulse Stevens Dep., at 107:7-108:2, attached as Exhibit M.

[24] See Subpoena to Produce Documents, Information, or Objects (Dec. 30, 2016), attached as Exhibit N.

[25] See VitaHEAT Medical's Written Objections to the Subpoena (Jan. 13, 2017), attached as Exhibit O.

[26] See id.

Plaintiffs, as a reasonable, safer, alternative design have no relevance in this case."[27]

The parties met and conferred on January 19, 2017.[28] VitaHEAT Medical did not dispute that 3M recently obtained exclusive rights to distribute the UB3; nor did VitaHEAT Medical challenge the fact that the UB3 provides conductive warming therapy to maintain patient normothermia in all surgical settings.[29] VitaHEAT Medical merely reiterated its threshold objection that the UB3 has no relevance whatsoever to the claims and issues in this litigation.[30] When Plaintiffs represented that they were in fact relying on the UB3, among other patient-warming devices, as a safer alternative design to the Bair Hugger, VitaHEAT Medical argued that conductive warming devices cannot be a safer alternative design because they are a different type of medical device altogether. Though Plaintiffs remained willing to narrow and clarify particular discovery requests, the parties agreed that it would be fruitless to wade into VitaHEAT Medical's objections to individual discovery requests before seeking judicial resolution of the global relevancy objection. Plaintiffs thus advised that they had no choice but to seek judicial intervention given VitaHEAT Medical's position.[31] Plaintiffs now move the Court to overrule VitaHEAT Medical's relevancy objection and to compel VitaHEAT Medical to comply with reasonable requests.

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[27] Id. at 1–2 (emphasis added).

[28] See Plaintiffs' Meet and Confer Letter to VitaHEAT Medical, LLC (Jan. 20, 2017), attached as Exhibit P.

[29] See id.

[30] See id.

[31] See id.

ARGUMENT

I. Rules 26(b) and 45(d) Govern VitaHEAT's Global Relevancy Objection.

Federal Rule of Civil Procedure 26(b)(1) provides that "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case." Fed. R. Civ. P. 26(b)(1); accord Orduno v. Pietrzak, Civ. No. 14-1393 (ADM/JSM), 2016 WL 5853723, at *2 (D. Minn. Oct. 5, 2016). The threshold requirement of discoverability is therefore met "if the information sought is relevant to the subject matter involved in the pending action." Orduno, 2016 WL 5853723, at *3 (citing Archer Daniels Midland Co. v. Aon Risk Serv., Inc. of Minn., 187 F.R.D. 578, 589 (D. Minn. 1999)). This Court broadly construes the term "relevancy" to mean "any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case." Coleman v. Nat'l Life Ins. Co., Civ. No. 13-2536 (JNE/FLN), 2014 WL 5860425, at *2 (D. Minn. Oct. 7, 2014) (Noel, J.). The broad relevancy standard applies with equal force where, as here, a nonparty objects to discovery. See Fed. R. Civ. P. 34(c); Fed. R. Civ. P. 45(d)(2)(B)(i) ("the serving party may move the court" where compliance is requested "for an order compelling production").

II. VitaHEAT's Global Relevancy Objection Has No Basis in Fact or Law.

Evidence of a safer alternative design is relevant to both the claims and issues in this multidistrict litigation. Plaintiffs not only alleged the widespread availability of safer alternative designs, but the UB3 is one of many safer alternative designs to the Bair Hugger.

Plaintiffs' Master Complaint repeatedly alleges that Defendants actively and aggressively marketed the Bair Hugger as safe in orthopedic surgeries despite their

knowledge of the risks of convective warming compared to conductive warming.[32] Still other paragraphs of the Complaint allege the availability of "conductive-warming" and "airflow-free warming technologies," which neither "increase[ ] bacterial contamination of operating rooms" nor "interrupt[ ] laminar airflow."[33] Plaintiffs even predicated Count II (Strict Liability – Defective Design and Manufacture), Count IV (Implied Warranty), and Count V (Minnesota Consumer Fraud Act) of the Complaint on the underlying fact that:

> At all times relevant to this action, economically and technologically feasible and safer alternative design existed for the Bair Hugger, including airflow-free warming technologies, which in reasonable medical probability would not have impaired the utility of the design and would not have prevented or significantly reduced the risk of Plaintiffs' infections and subsequent injuries.[34]

These facts were alleged for a reason. Proving an alternative design is the rule in many but not all product defect cases.[35] The Restatement (Third) of Torts on Products

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[32] See Pls.' Master Long Form Compl. ¶¶ 10, 52, 58, 61, 95, 99, 114–15, 128.

[33] See id. ¶ 95 (emphasis added); see also id. ¶¶ 58, 61.

[34] See id. ¶ 95 (Strict Liability – Defective Design and Manufacture); see also id. ¶¶ 114–15 (Breach of Implied Warranty), ¶ 128 (Minnesota Consumer Fraud Act).

[35] Compare, e.g., Dancy v. Hyster Co., 127 F.3d 649, 654 (8th Cir. 1997) (Arkansas law requires a plaintiff to bear "the burden of proving the existence of a defect by showing that a safer alternative design actually exists"); Hernandez v. Tokai Corp., 2 S.W.3d 251, 256–57 (Tex. 1999) (similar requirement under Texas law); Gebhardt v. Mentor Corp., 191 F.R.D. 180, 185 n.2 (D. Ariz. 1999) (Arizona law); Truchan v. Nissan Motor Corp., 720 A.2d 981, 986 (N.J. 1998) (New Jersey law); Pries v. Honda Motor Co., 31 F.3d 543, 545 (7th Cir. 1994) (Indiana law); with, e.g., Kallio v. Ford Motor Co., 407 N.W.2d 92, 96–97 (Minn. 1987) (questioning the safer alternative design requirement); see also Michael V. Ciresi & Gary L. Wilson, A Misstatement of Minnesota Products Liability Law: Why Minnesota Should Reject the Requirement that a Plaintiff Prove a Reasonable Alternative Design, 21 WM. MITCHELL L. REV. 369 (1995).

Liability, for example, makes proof of a reasonable alternative design the very heart of a *prima facie* design defect case.[36] In jurisdictions which have adopted the Restatement (Third) of Torts, then, Plaintiffs generally (but not always) bear the burden of proving a "reasonable alternative design" was available to Defendants.[37] It therefore stands to reason that Plaintiffs' discovery requests regarding "alternative designs are reasonably calculated to lead to the discovery of admissible evidence." Honeywell Int'l Inc. v. ICM Controls Corp., No. 11-CV-569 (JNE/TNL), 2013 WL 12139845, at *6 (D. Minn. Sept. 24, 2013).[38]

In re Mentor Corp. proves the point. In that multidistrict litigation, plaintiffs alleged defective design claims against the manufacturer of a medical product. See In re Mentor Corp. ObTape Transobturator Sling Prod. Liab. Litig., No. 4:08-MD-2004 (CDL), 2010 WL 234797, at *1 (M.D. Ga. Jan. 14, 2010). After plaintiffs subpoenaed a third-party

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[36] See Restatement (Third) of Torts: Product Liability § 2(b) ("[A] product is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.").

[37] Id. cmt. b.

[38] See Ponder v. Warren Tool Corp., 834 F.2d 1553, 1559 (10th Cir. 1987) ("The existence of safer alternative designs is relevant under both [state] and federal law on the question whether a product is defective.") (collecting federal case law); see also Lloyd v. John Deere Co., 922 F.2d 1192, 1195 (5th Cir. 1991) (noting that "alternative designs and industry standards are relevant to whether a product is reasonably fit or unreasonably dangerous"); Kuennen v. Wright Med. Tech., Inc., No. C14-2045, 2015 WL 795032, at *4 (N.D. Iowa Feb. 25, 2015) ("Given the broad scope of relevancy in the discovery context, the Court concludes that evidence regarding alternative designs is relevant to both Plaintiffs' claims and Defendant's defense."); Brownlow v. General Motors Corp., No. 3:05-CV-414-R, 2007 WL 2712925, at *7 (W.D. Ky. Sept. 13, 2007) ("Information relating to the feasibility and effectiveness of alternative designs, and GM's knowledge of potentially safer designs, is highly relevant and thus discoverable.").

manufacturer of a medical device that allegedly provided a safer alternative design, the third-party moved to quash the subpoena because the discovery was "not relevant" to the case. Id. The MDL court denied the motion under the broad relevancy requirements of Rule 26(b)(1). Id. at *1–2. Because "[e]vidence of a feasible and safer alternative design [was] clearly relevant to [p]laintiffs' design defect claim," the court concluded that plaintiffs' discovery requests "satisf[ied] the threshold burden of establishing relevance." Id. at *2.

So too here. Just as plaintiffs in Mentor Corp. sought discovery from a third-party manufacturer of a medical device that allegedly provided a safer alternative design to the device at issue in that case, Plaintiffs here seek discovery from VitaHEAT Medical, a manufacturer of a patient-warming device that provides a safer alternative design to the Bair Hugger. Just as the third-party manufacturer in Mentor Corp. argued that nonparty discovery was not relevant to the litigation, VitaHEAT Medical argues here that discovery as to the UB3 has no relevance whatsoever to the claims or issues in this litigation. And just as the MDL court in Mentor Corp. rejected the third-party manufacturer's argument regarding the non-relevancy of the plaintiffs' discovery requests, this Court should follow suit. After all, just as plaintiffs in Mentor Corp. alleged the availability of safer alternative designs in their complaint, Plaintiffs here have alleged in their Master Complaint that "airflow-free" devices provide a safer alternative design, and the UB3 is one such design.

VitaHEAT Medical cannot cogently argue otherwise. [redacted]

[redacted][39]

[redacted]

[redacted]

[redacted][40] [redacted][41]

The UB3 perfectly fits that "ideal" yet "alternative" technology. VitaHEAT Medical cannot obfuscate that fact simply to avoid discovery. VitaHEAT Medical's website claims the UB3 uses "conductive heat [to] warm patients without circulating air."[42] In addition, the President and CEO of VitaHEAT Medical touted the UB3 as both a "safe" and "cost efficient" device that uses "patented conductive ink technology in a thin mattress design" to "prevent patient hypothermia" in not only some surgical settings but "all perioperative phases."[43] Comparing the UB3 to forced-air warming systems, he ultimately exclaimed:

> We are excited to offer this innovative solution that helps prevent patient hypothermia. Not only has our system been proven as effective as currently used forced-air patient warming solutions, it is safe and cost efficient.[44]

The President's statements, moreover, mirrored the company's claims to the FDA. Like the 510(k) filings for each and every model of the Bair Hugger, the 510(k) filings for

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[39] See, e.g., 3MBH00554405 (emphasis added), attached as Exhibit D.

[40] Id. (emphasis added).

[41] Id. (emphasis added).

[42] See VitaHEAT Medical Homepage (website no longer available), attached as Exhibit B.

[43] See, e.g., Press Release, VitaHEAT Medical (Jan. 12, 2016), attached as Exhibit C.

[44] See id. (emphasis added).

the UB3 proclaim that the device "treats hypothermia" and "provides warmth to patients."[45] What's more, the 510(k) filings for the UB3 predicate its "indications for use" and "technological characteristics" upon none other than the "Hot Dog Patient Warming Mattress System by Augustine Biomedical & Design LLC"[46]—the same device and the same company that Defendants have pursued discovery from at all steps of this litigation.[47]

Blackwell Burke P.A. cannot play discovery one way on behalf of Defendants, yet switch its cards simply to suit VitaHEAT Medical. To do so amounts to nothing more than classic *tu quoque*. Nor can VitaHEAT Medical materially distinguish the UB3 from either the Hot Dog or the Bair Hugger based on the bare bones fact that the UB3 can be used in "mobile" situations.[48] Such *ipse dixit* founders on the shoals of the company's broad statements to the public and the FDA.[49] See, e.g., Krumm v. Bar Maid Corp., Civ. No. 11-

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[45] See VitaHEAT Medical's 510(k) Summary, at *1 (Oct. 4, 2013), attached as Exhibit Q.

[46] See, e.g., id. at *6 ("The VITAHEAT device has the same indications for use, [and] similar scientific fundamental technology, materials and packaging as the predicate device. The VITAHEAT device has very similar technological characteristics to the predicate and both have the same general shape, size, and identical principles of use.").

[47] See In re Bair Hugger Forced-Air Warming Products Liab. Litig., No. 15-md-2666 (JNE/FLN), Dkt. No. 128 (Defs.' Mot. to Compel Third-Party Augustine Entities to Produce Docs. in Response to Subpoenas); see also id., Dkt. No. 182 (Defs.' Mot. to Compel Production of Docs. on Augustine's Privilege Log).

[48] See VitaHEAT Medical's Written Objections to the Subpoena, at *1 (Jan. 13, 2017), attached as Exhibit O.

[49] See VitaHEAT Medical's 510(k) Summary, at *6 ("Although there are certain difference between the VitaHEAT device and the predicate, these differences do not raise any concerns in terms of safety and efficacy."), attached as Exhibit Q.

2782 (JNE/SER), 2013 WL 3064442, at *5 (D. Minn. June 18, 2013) (rejecting defendant's argument that a device was not a "feasible, safer alternative design" because defendant failed to explain how the device was "meant to be used in a completely different way").[50]

At the end of the day, 3M acquired exclusive rights to distribute the UB3, a patient-warming device that is just as effective[51] but much less risky than blowing dirty air onto patients.[52] That allegation alone, even if disputed by Defendants and VitaHEAT Medical,

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[50] Just as Defendants objected to Plaintiffs' Notice of Rule 30(b)(6) Deposition, Plaintiffs suspect that VitaHEAT Medical will cite Massa v. Genentech, Civ. No. H-11-70, 2012 WL 956192, at *7 (S.D. Tex. Mar. 19, 2012), and Burks v. Abbott Labs., Civ. No. 08-3414 (JRT/JSM), 2010 WL 1576779, at *4 (D. Minn. Apr. 20, 2010), for the proposition that "[t]he VitaHEAT UB3 system cannot be a feasible safer alternative design to the Bair Hugger system because it is a different product that employs an entirely different kind of warming: conductive warming." See Defendants' Objections to Plaintiffs' Notice of Rule 30(b)(6) Deposition, at *4–5, attached as Exhibit R. Neither Massa nor Burks involved simple discovery requests where, as here, Plaintiffs have easily shown the relevancy of the requests, while Defendants have simultaneously sought discovery from Augustine Biomedical & Design LLC as to the Hot Dog patient-warming device. Not to mention that Massa and Burks both flout the well-established fact that "a safer design alternative [may be] implemented in other products." See, e.g., Block v. Toyota Motor Corp., 5 F. Supp. 3d 1047, 1067 (D. Minn. 2014) (emphasis added). This Court should therefore refuse to draw a "magic line of demarcation whereby suggested alteration constitutes an alternative product rather than an alternative design." Sec. Nat'l Bank of Sioux City v. Abbott Labs., No. 11-CV-4017 (DEO), 2012 WL 327863, at *10 (N.D. Iowa Feb. 1, 2012). The only difference between the Bair Hugger and the UB3 is the type of heating technology; the end result is still and always patient warming. See id. (rejecting Burks along with the same argument that VitaHEAT Medical will very likely raise in opposition to the instant motion).

[51] See, e.g., 3MBH01566286–97 (randomized study of 50 patients undergoing outpatient orthopedic procedures found "no difference between intra-operative and recovery temperatures between patients using either a forced-air warming device [3M's Bair Hugger] or a conductive heating device [VitaHEAT's UB3]"), attached as Exhibit K.

[52] See, e.g., VitaHEAT Medical's Homepage ("There is no forced air to warm up clinicians tending the patients." The UB3 therefore "meets all FDA safety requirements," and it uses "conductive heat [to] warm patients without circulating air."), attached as Exhibit B; see also Pls.' Master Long Form Compl. ¶¶ 58, 61, 95.

is dispositive of the relevancy of Plaintiffs' request to obtain discovery targeted specifically at the UB3. See, e.g., Std. Fire Ins. Co. v. Broan Nutone, LLC, No. 2:07-cv-44 (KS/MTP), 2008 WL 5560882, at *6 (S.D. Miss. July 1, 2008) ("A competitor's contemporaneous use of the proposed design alternative for the same purpose in the same consumer market is sufficient evidence to establish a genuine issue of fact as to the existence of a feasible design alternative."). The Court should thus grant Plaintiffs' motion to overrule VitaHEAT Medical's global relevancy objection and to compel VitaHEAT Medical to comply with the subpoena. See, e.g., Cardenas v. Dorel Juvenile Group, Inc., 230 F.R.D. 611, 615–17 (D. Kan. 2005) (granting motion to compel production of information concerning a product where the challenged discovery was relevant to the feasibility of an alternative design).

CONCLUSION

In the words of the law firm that represents VitaHEAT Medical and Defendants in this litigation: "Discovery under the Federal Rules of Civil Procedure is permissive, authorizing parties to obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case."[53] The Court should apply those words with equal force here and grant Plaintiffs' motion to overrule VitaHEAT Medical's global relevancy objection and to compel VitaHEAT Medical to comply with reasonable requests. The UB3 is relevant to the claims and issues in this case.

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[53] See In re Bair Hugger, Dkt. No. 130 (Defs.' Mot. to Compel Third Party Augustine Entities to Prod. Docs. in Response to Subpoenas), at *14.

Respectfully submitted,

Dated: February 9, 2017

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